Interview Summary	Application No.	Applicant(s)	
	09/829,707	MORRISON, JAMES U.	
	Examiner	Art Unit	
	EVERETT WHITE	1623	

All participants (applicant, applicant's representative, PTO personnel):

(1) *EVERETT WHITE*. (3)*Mr. MORRISON*.

(2) *N. NICOLE ENDEJANN*. (4)_____.

Date of Interview: *11 June 2003*.

Type: a)☒ Telephonic b)☐ Video Conference
c)☐ Personal [copy given to: 1)☐ applicant 2)☐ applicant's representative]

Exhibit shown or demonstration conducted: d)☒ Yes e)☐ No.
If Yes, brief description: *A Draft/Proposed Amendment*.

Claim(s) discussed: *1-43*.

Identification of prior art discussed: *The prior art of record*.

Agreement with respect to the claims f)☐ was reached. g)☒ was not reached. h)☐ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: *The draft/proposed amendment, previously faxed to the Examiner, was discussed. The Examiner indicated that the proposed amendment to the claims in the draft would put the claims in better condition for appeal, but an indication of allowance for the application base on the claims in the Draft amendment is not possible at this time. A copy of the Draft amendment is attached hereto*.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

_____
Examiner's signature, if required

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record
A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews
Paragraph (b)
In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.
All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:
- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:
1) A brief description of the nature of any exhibit shown or any demonstration conducted,
2) an identification of the claims discussed,
3) an identification of the specific prior art discussed,
4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
5) a brief identification of the general thrust of the principal arguments presented to the examiner,
   (The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
6) a general indication of any other pertinent matters discussed, and
7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

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Client/Matter: 26017.6

If you do not receive a complete transmission, please call: (216) 363-4605

Number of pages (including this page): 10

U. S. Serial No. 09/829,707

Dear Examiner White:

Per our conversation, attached is the draft amendment.

We look forward to talking to you Wednesday June 11, 2003 at 2:30. Thank you for your time.

N. Nicole Endejann

DRAFT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	James U. Morrison	Examiner:	White, Everett
Application No.:	09/829,707	Group Art:	1778
Filing Date:	April 10, 2001	Docket No.:	26017-3 (old) 26017-6 (new)

Title: METHOD AND COMPOSITION FOR CONTROLLED RELEASE ACARBOSE FORMULATIONS

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

AMENDMENT B AND RESPONSE TO FINAL OFFICE ACTION

Dear Sir:

This is in response to the final Office Action dated March 7, 2003, issued in connection with the above-referenced application. The Office Action set a three-month shortened statutory period to respond. Accordingly, this response is timely filed. However, the Commissioner is hereby authorized to change any fees which may be due in connection with this Response, or credit any overpayment, to Deposit Account No. 02-2051 referencing Attorney Docket No. 26017-6. Please amend the subject application as follows:

IN THE CLAIMS:

Please cancel claims 1-14 and 28-42.

Claims 1-14 (Canceled)

15. (Currently Amended) A chemical composition used to stimulate weight loss in a patient, **consisting essentially of** ~~comprising~~ :

acarbose; and

a sustained release matrix, wherein said acarbose and sustained release matrix are combined to form a mixture.

16. (Original) The composition of claim 15, wherein said acarbose is about 20% to about 40% by weight of said composition.

17. (Original) The composition of claim 15, wherein said acarbose is present in an amount of about 25mg to about 300mg.

18. (Currently Amended) The composition of claim 15, further **consisting essentially of** ~~comprising~~ a filler.

19. (Currently Amended) The composition of claim 18, further **consisting essentially of** ~~comprising~~ a glidant.

20. (Currently Amended) The composition of claim 19, further **consisting essentially of** ~~comprising~~ a lubricant.

21. (Original) The composition of claim 19, wherein said glidant is selected from the group consisting of colloidal silica and precipitated silica.

22. (Original) The composition of claim 20, wherein said lubricant is selected from the group consisting of sodium lauryl sulfate, sodium stearyl fumarate, and metal stearates.

23. (Original) The composition of claim 20, wherein said lubricant is selected from the group consisting of magnesium stearate, zinc stearate, calcium stearate, and mixtures thereof.

24. (Original) The composition of claim 15, wherein said sustained release matrix is hydroxypropylmethylcellulose (HPMC).

25. (Original) The composition of claim 15, wherein said composition is covered with a coating.

26. (Original) The composition of claim 25, wherein said coating is a cellulose ether-based coating.

27. (Original) The composition of claim 25, wherein said coating is a cellulose ether-based coating in combination with ethyl cellulose.

Claims 28-42 (Canceled)

43. (Previously Added) A method of treating a patient to stimulate weight loss comprising administering an acarbose formulation to the patient, wherein such formulation does not include a lipase inhibitor.

REMARKS

Applicant wishes to thank the Examiner for the consideration given this case to date. Applicant has had an opportunity to carefully consider the Examiner's action and in an effort to place the application in condition for allowance, or alternatively, to remove issues and present the claims in better form for consideration on appeal, Applicant has canceled claims 1-14 and 28-42, and has amended claims 15-27.

Applicant has addressed only the rejections pertaining to claims 15-27 and 43 below, in light of this amendment. Presently, claims 15-27 and 43 are pending. In light of the foregoing and the remarks below, Applicant respectfully submits that this Amendment after final should be entered and the instant claims passed to issuance.

THE EXAMINER'S ACTION

In the Office Action dated March 7, 2003, the previous rejections were maintained, specifically the Office:

rejected claim 43 under 35 U.S.C. § 112, first paragraph as setting forth new matter;

rejected claims 1-14 under 35 U.S.C. § 102(e) as being anticipated by Patel et al., U.S. Patent No. 6,309,663;

rejected claims 15-27 under 35 U.S.C. § 102(e) as being anticipated by Patel et al.;

rejected claims 28-41 under 35 U.S.C. § 102(b) as being anticipated by Bremer et al., U.S. Patent No. 5,643,874;

rejected claims 15-27 under 35 U.S.C. § 102(b) as being anticipated by Bremer et al., the '874 reference; and

rejected claims 28-42 under 35 U.S.C. § 103(a) as being unpatentable over Bremer et al. in view of Patel et al.

REJECTIONS UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

The Office rejected claim 43 under 35 U.S.C. 112, first paragraph as containing new matter. Specifically, the Office has taken the position that the previously added claim 43 that recites a method of administering a composition that "does not include a lipase inhibitor" is not

supported by the specification. Applicant has in fact provided written support for such a claim by including examples of such a formulation. Applicant includes multiple examples of a composition of sustained release matrix, namely HPMC, and acarbose (See Spec. pg. 2, lns. 18-19, pg. 8, lns. 11-12). As described, such a composition does not contain any other active ingredient, including a lipase inhibitor. The fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed. *See, e.g., Vas-Cath, Inc.*, 935 F.2d at 1563-64, MPEP § 2163. Examples of a composition containing only HPMC and acarbose and examples of a method of use of such a composition provide a written description of the subject matter of claim 43 and conveys with reasonable clarity to one skilled in the art that the Applicant was in possession of a method to stimulate weight loss by administering a formulation of acarbose and a sustained release matrix, wherein such a formulation does not contain a lipase inhibitor. As such, Applicant respectfully submits that the rejection should be withdrawn.

REJECTIONS UNDER 35 U.S.C. § 102(e)

The Office also maintained the rejection of claims 15-27 as being anticipated by Patel, stating that Patel discloses a composition comprising surfactants and a hydrophilic therapeutic agent, such as acarbose (See First Office Action, pg. 3).

Applicant's amended claim 15 calls for a composition of acarbose and a sustained release matrix to form a mixture. As defined in the specification and recited in the claims, the sustained release matrix causes constant release of the acarbose over a period of time (See Spec. pg. 2, lns. 14-17) Patel does not teach that which is encompassed by claims 15-27 because Patel does not disclose a combination of acarbose and a sustained release matrix, which necessarily causes constant release of acarbose, in a mixture.

In light of the amendments, the scope of the claims is limited to a composition of acarbose and a sustained release matrix. Patel discloses a composition comprising at least two surfactants and a hydrophilic therapeutic agent, such as acarbose (Col. 4, lns. 1-5). Patel's composition includes additional components including at least two surfactants. Applicant's

claims exclude such components because the introduction of the additional at least two surfactants "materially affect the basic and novel characteristics" of the claimed invention, therefore Patel does not anticipate the instant claims. *In re Herz*, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976) (emphasis in original).

Additionally, it is respectfully submitted that although Patel discloses that the combination of two surfactants and a therapeutic agent may be "enteric coated" which relates to "a mixture of pharmaceutically acceptable excipients which is applied, combined with, mixed with or otherwise added to the hydrophilic therapeutic agent," this is only used to definitionally broaden the idea of a coating. (Col. 38, lns. 53-57). However, this enteric coating is not sustained release matrix, which alters the rate and extent of release, but rather an excipient altering the location of the release of the agent. As Patel states, the enteric coating causes release of the therapeutic agent in the lower gastrointestinal tract. (Col. 38, lns. 36-43). Patel does not disclose or suggest that the enteric coating is a sustained release matrix, nor does Patel teach or suggest acarbose "mixed with" a sustained release matrix.

Patel also discloses "a coated multiparticulate composition." (Col. 38, lns. 12). However, Applicant has not claimed a "coated multiparticulate composition," but rather a composition of acarbose and a sustained release matrix. In addition, Patel does not disclose a sustained release matrix.

Patel also discloses that the "enteric coating" may be applied through aqueous dispersion. (Col. 38, lns. 61-63). Again, it is respectfully submitted that Patel does not teach that the enteric coating is a sustained release matrix. Furthermore, Applicant has not claimed that the sustained release matrix is applied through an aqueous dispersion. In fact, the specification teaches that acarbose and a sustained release matrix are preferably dry mixed (See Spec. pg. 7, lns. 5-6).

The composition disclosed by Patel necessarily involves an uneven, uncontrolled release of the therapeutic agent. As the coating of Patel dissolves, the composition is released, or essentially leaks out of the coating at an uneven, uncontrolled rate. This discontinuous dissolution causes spikes in the therapeutic concentration of the active ingredient in the patient.

It is respectfully submitted that the Applicant's combination of acarbose and a sustained release matrix achieves a true sustained release of the composition. As defined in the

specification, the sustained release matrix causes constant release of the acarbose over a predetermined period of time (See Spec. pg. 2, lns. 14-17). That is, the composition, as embodied in claim 15, provides a constant, controlled release of the composition. Patel's composition of at least two surfactants and a therapeutic agent, such as acarbose, does not include a sustained release matrix, such that constant release of the composition is achieved. Furthermore, Applicant's composition is limited to the active ingredient, acarbose, and a sustained release matrix. In contrast, Patel's composition contains a therapeutic agent and at least two surfactants. As Patel discloses, the additional at least two surfactants materially alter the characteristics of the composition by causing increased absorption (Col. 4, lns. 50-59). As such, it is respectfully submitted that claims are not anticipated by Patel et al. and the rejection should be withdrawn.

REJECTIONS UNDER 35 U.S.C. § 102(b)

The Office maintained the rejection of claims 15-27 as being anticipated by Bremer et al. The Office states that Bremer discloses a composition of glucosidase and/or amylase inhibitors in combination with a lipase inhibitor in the treatment of obesity (See First Office Action pg. 5). The Office further asserts that because Applicant's have not claimed acarbose alone to stimulate weight loss, Bremer's disclosure does not teach away from Applicant's method of treating a patient to stimulate weight loss comprising administering an acarbose formulation to the patient (See Office Action pg. 4).

As amended, Applicant has claimed a composition of acarbose and a sustained release matrix alone to stimulates weight loss. The language set forth in the amended claims excludes the presence of other active ingredients in the claimed composition. In light of the fact that Bremer states that glucosidase and/or amylase inhibitors, *used in monotherapy* in combination with a reduction diet bring about "practically no weight loss," but that in combination with a lipase inhibitor does stimulate weight loss, necessarily teaches that the lipase inhibitor is an active ingredient (Col. 4, lns 23-26). Since Bremer's composition includes the active ingredient of a lipase inhibitor, it does not anticipate the instant claims.

Furthermore, Bremer does not disclose a composition of acarbose and sustained release matrix. As the specification discloses, the sustained release matrix, which is uniformly mixed with acarbose, causes a constant, controlled release of the composition over a predetermined period of time and such release occurs in the lower gastrointestinal tract (See Spec. pg. 2, lns. 14-17). In contrast, the composition of Bremer which includes among other things, HPMC, only causes release and increased residence time in the stomach (Col 6, Ex. D). Bremer's formulation as used in Example D did not result in a controlled, constant release of the formulation in the lower gastrointestinal tract.

Applicant submits Bremer does not teach the use of an acarbose and sustained release matrix composition. Applicant's disclosure states that a composition of acarbose and a sustained release matrix, in and of itself, will result in the stimulation of weight loss in a subject. Bremer clearly teaches away administering a composition of acarbose and no other active ingredients for stimulating weight loss (Col. 4, lns 23-26). Based on Bremer's disclosure, one of ordinary skill in the art would not expect that administering only a formulation of acarbose, as claimed by Applicant, would stimulate weight loss. Furthermore, it is the combination of acarbose and a sustained release matrix which results in weight loss, since administration of acarbose alone does not result in weight loss. As such, the rejection should be withdrawn.

Conclusion

In light of the foregoing, Applicant respectfully submits that the claims are patentable over the references of record and are thus in condition for allowance. Applicant respectfully requests an early indication thereof.

Respectfully submitted,

DRAFT

Dated: _____ By: _____

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